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INTERVET INC. PATENT DEPARTMENT PO BOX 318 MILLSBORO, DE 19966-0318				
EXAMINER				
PORTNER, VIRGINIA ALLEN				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

09/904,994

**Applicant(s)**

KUSTERS ET AL.

**Examiner**

GINNY PORTNER

**Art Unit**

1645

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 60,62-66 and 82 and 71,74,76-79,81,83 and 84 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 60,62-66 and 82 is/are allowed.
- 6) ☒ Claim(s) 71,74,76-79,81,83 and 84 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

New claims 60, 62-66, 71, 74-84 are pending.  
Objections and rejections over canceled claims are rendered moot.

#### *Objections/Rejections Withdrawn*

1. ***Withdrawn, Claim Rejections - 35 USC § 112 Amended*** Claims 60, 62-66, 71, 74-81 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, is herein withdrawn in light of Applicant's claim amendments to recite ---over the entire length---.
2. ***Withdrawn, Claims 75 and 80 rejected*** under 35 U.S.C. 102(b) as being anticipated by Gootz et al (1994) as is herein withdrawn because the claims have been canceled.
3. ***Withdrawn, Claim Rejections - 35 USC § 101*** Claims 64-66 are no longer directed to non-statutory subject matter in light of Applicant's definition in [0029] "the technique of in vivo homologous recombination, well-known in the art, can be used to introduce a recombinant nucleic acid sequence into the genome of a bacterium, parasite or virus of choice, capable of inducing expression of the inserted nucleic acid sequence according to the invention **in the host animal**", which describes the invention to include animals with recombinant host cells that express the heterologous recombinant nucleic acid sequences. The claims have been amended to recite "An isolated host cell".
4. ***Withdrawn, Claim Objections*** Claims 62-66, 75-76 and 80-81 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim has been addressed and obviated by claim amendment of independent claim 60, 71 and 77.

#### *Response to Arguments for Objections/Rejections Maintained*

5. Applicant's arguments filed March 7, 2008 have been fully considered but they are not fully persuasive. The isolated nucleic acid claims have been indicated as allowable, but the isolated polypeptides have not.
6. Applicant states the claims have been amended and submit the application is in condition for allowance. In light of various amendments of the claims, some of the objections and rejections have been obviated, but others will be maintained and addressed below.

***New Grounds of Rejection***

Please Note: Upon reconsideration of the disclosure of the prior art the following references are being applied to the claims.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Reinstated, ***Claim Rejections - 35 USC § 102*** Claims 71, 74, 76-79, 81, 83-84 are rejected under 35 U.S.C. 102(b) as being anticipated by Gootz et al (1994).

9. Gootz et al produced the claimed and disclosed polypeptides and compositions that comprise the polypeptide (instant claims 76 and 81), wherein the polypeptides were isolated by gel electrophoresis (see Fig. 2, SDS-PAGE, col. "a").

10. Two bands are shown in the gel of Figures 2 and 3) about 66 and 70 kDa for *H. felis* CS-1 urease and an additional band of about 31 kDa. While Gootz et al do not refer to these urease polypeptides of *Helicobacter felis* as urease X and urease Y, these polypeptides are the same or equivalent polypeptides now claimed because the urease subunits were isolated from *H. felis* strain ATCC 49179 (see page 794, col. 1, p. 2, line 1), which is a strain also known as CS-1. The urease was extracted from the surface of *H. felis* (see page 794, co. 1, p. 5) and dialyzed against PBS and fractioned in Tris-HCl pH 8 elution buffer. The phrase "at least 99% identical" recited in claim 74 encompasses polypeptides that share 100% identity with SEQ ID NO 2, which is the

inherent amino acid sequence of a urease subunit polypeptide obtained from strain CS-1(ATCC49179) shown in figures 2 and 3, lane a.

11. Gootz et al chose *H. felis* ATCC 49179 (see abstract), also known as CS-1, the identical strain Applicant used to determine the sequence for urease as shown in Figure 1(a), SEQ Id NO 1 and isolated and purified the *Helicobacter felis* urease polypeptide (see Gootz et al, page 794, col. 1, paragraph 5), showed antibody compositions immunoreactive with the polypeptides (see Gootz et al, page 794, col. 2, paragraph 4, and Figure 3, page 795) a

12. While Gootz et al do not disclose the amino acid sequence, of the *H. felis* polypeptide for the *H.felis* CS-1 urease, by all comparable data the polypeptide to which the antibodies immunoreact are the same or equivalent compositions now claimed produced by a different process, but obtained from the identical *Helicobacter felis* source as Applicants. The amino acid sequence and nucleic acid sequence of a polypeptide and nucleotide molecule, respectively, are descriptors of inherent structural residues of the polypeptide and DNA of Gootz et al. Discovery of a new descriptor of an already known product does not define a novel or unobvious product.

Gootz et al still inherently anticipates the instantly claimed invention. *Atlas Powder Co. v IRECA*, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

13. Claims 71, 74, 76-79 and 81 rejected under 35 U.S.C. 102(b) as being anticipated by Jalava et al, October 1998).

Jalava et al disclose isolated *Helicobacter felis* polypeptides that have urease activity (see Table 3 (urease positive), page 3999, col. 1, last paragraph "extraction, separation, and numerical analysis of whole-cell proteins (see Figure 3, page 4004)), the urease polypeptides being CS-1 urease polypeptides (see CCUG 28539, also known as CS-1 (see Table 1, page 4000)), and variants of the CS-1 polypeptides produced by other strains of *Helicobacter felis* (see Figure 3, strain Hellu, a phylogenically similar strain, see Figure 2, CCUG 28359 and Hellu). The pharmaceutically acceptable carrier was either the extraction buffer, gel or gel buffer (see page 3999, col. 1, last paragraph "protein extract and electrophoresis).

- Therefore the variant *Helicobacter felis* urease polypeptides of Jalava et al were isolated from variant strains of *Helicobacter felis* that evidenced urease positive activity; the isolated *H. felis* urease variant polypeptides inherently anticipate the instantly claimed invention as now claimed.
- Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594
- Inherently the reference anticipates the now claimed invention. *Atlas Powder Co. v IRECA*, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously

unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

***Allowable Subject Matter***

14. Claims 60, 62-66 and 82 define over the prior art of record and are allowed.

***Conclusion***

***15. This is a non-final action.***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginny Portner/  
Examiner, Art Unit 1645  
May 19, 2008

/Mark Navarro/  
Primary Examiner, Art Unit 1645